DETAILED ACTION

Claims 1-4 and 11-28 are pending.

Election/Restrictions

Applicant's election of Group I (claims 1-4 and 11-22) in the reply filed on 12/3/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 23-28 are withdrawn from consideration as being drawn to non-elected subject matter. Claims 1-4 and 11-22 have been considered on the merits.

Claim Objections

Claim 1 is objected to because of the following informalities: the range of EGF in the claim is disclosed as "0.5 to 50.ng/ml." It appears to be "0.5 to 50.0 ng/ml." Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The current claims contain the trademark/trade name OptiPro®. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35

U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a basic culture medium and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 11, 12, 16-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Cancedda et al. (WO 00/27996; IDS ref.) in light of Sigma Production Information (F-12 Coon's modification; 2009).

Cancedda et al. teach a culture medium for chondrocyte cells and the medium comprises a base minimum essential medium (MEM) such as Coon's modified Ham's F12 medium supplemented with EGF (1-10 ng/ml), PDGF (1-10 ng/ml), FGF (1-10 ng/ml), IGF (5 ng/ml), dexamethasone (10^{-8} M = ~4 ng/ml; calculated based on MW of dexamethasone at 392.47) (p.3-4; Table 1 at p.6; Table 2 at p.7). It is an inherent property of the Coon's modified Ham's F12 medium to contain L-glutamine at the concentration of 0.292 g/L, which is approximately 2 mM (calculated based on MW of

glutamine at 146.15), according to Sigma (product information).

With regard to the limitation of human serum additionally added to the medium at the concentration up to 15% (w/v) in claims 11, 12 and 19-21, the claims are interpreted at 0% of human serum (no addition) since the range disclosed in the claims encompasses 0% up to 15% of human serum, and it includes no addition of human serum.

Thus, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4 and 11-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Min et al. (US 6,558,949) in view of Cancedda et al. (supra) and D'Lima et al. (2001) in further view of Marshak et al. (US 5,908,782).

Min et al. teach a culture medium for culturing chondrocytes comprising a basic

medium such as DMEM or Ham's F-12 media, human serum at 1-50% and growth factors such as IGF, FGF, PDGF an EGF at the concentration of 1-10 μg/L (1-10 ng/ml) (col. 2, lines 12-37). Since it is extremely well known that DMEM or Ham's F-12 media typically contains L-glutamine at a concentration of 2-4 mM, it is considered that the Min et al.'s medium comprises glutamine at the claimed concentration.

Min et al. do not teach dexamethasone in the culture medium.

Cancedda et al. teach dexamethasone as a supplemental steroid to the culture medium for chondrocytes (col. 2, line 44), and the concentration of dexamethasone being 10^{-8} M (~4 ng/ml).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to use dexamethasone as a supplemental steroid in the medium of Min et al.

The skilled artisan would have been motivated to make such a modification because Cancedda et al. teach that dexamethasone keeps the cells in a cycling phase in vitro (col. 2, lines 50-51), and furthermore, it is well known in the art that dexamethasone decreases apoptosis rate of chondrocytes in culture according to D'Lima et al. (p.25, right col.). Therefore, a person of ordinary skill in the art would recognize the benefit of dexamethasone in culturing chondrocytes and be motivated to use dexamethasone in the medium of Min et al. with a reasonable expectation of success.

With regard to the limitation drawn to the concentration of dexamethasone being 10-60 ng/ml or 40 ng/ml, the concentration of composition in the medium of Min et al. in

view of Cancedda et al. and D'Lima et al. would be considered as a result-effective variable, and as such, the variable can be routinely optimized within the workable range of the concentration. It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to optimize the concentration of dexamethasone to obtain desired outcome in using the cell culture medium for chondrocytes or cartilage cell. Furthermore, Marshak et al. teach the concentration of dexamethasone used in the culture medium being 10^{-7} M, which is approximately 40 ng/ml (col. 9, lines 10-12).

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is (571)272-9041. The examiner can normally be reached on 8:00 am - 4:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Taeyoon Kim/
Examiner, Art Unit 1651